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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,442	03/07/2002	Masafumi Tsujimoto	001560-332	9751

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/091,442	Applicant(s) Tsujimoto et al	
	Examiner Mark Navarro	Art Unit 1645	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
 Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-33 is/are pending in the application.

4a) Of the above, claim(s) 1-15 and 22-27 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 16-21 and 28-33 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>7</u>	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6) <input type="checkbox"/> Other: _____
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DETAILED ACTION

Election/Restriction

1. Applicant's election of Group II, claims 16-21 and 28-31 in Paper No. 10, received June 3, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Additionally, Applicants amendment filed June 3, 2003 has been received and entered. Newly filed claims 32-33 have been added. Consequently, claims 1-33 are pending in the instant application, of which claims 1-15 and 22-27 are withdrawn from further consideration as being drawn to a non-elected invention.

Claim Objections

2. Claim 28-29 are objected to under 37 CFR 1.75(c) as being in improper form because a claim cannot depend upon different sets of claims for different features. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

3. Claims 20-21, 28, 31 and 33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *in vitro* production of a megakaryocyte differentiation

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factor, does not reasonably provide enablement for production of this factor in a transgenic animal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 28 recites “culturing a host” and claim 29 indicates that the host is the silkworm *Bombyx mori*. The claims as written include transgenic production of the megakaryocyte differentiation factor. The specification on page 15 discloses appropriate eukaryotic and prokaryotic host cell lines and the statement that insects *per se* may be used, but there does not appear to be any disclosure of transgenic production in animals or plants. It is noted with respect to claim 29 that the specification discloses using a cell line from this silkworm. The specification does disclose infecting *Bombyx mori* larvae with baculovirus containing the DNA encoding the desired protein and sacrificing the insects to recover the produced protein from the hemolymph. (Example 4). This example does not enable transgenic production.

US Patent Application Publication 2002/0104112 sets forth that many transgenes have deleterious effects on the cells of the transgenic animal in which they are expressed; thus, it is difficult to construct transgenic animals expressing these genes. Furthermore, many promoters are “leaky” resulting in minimal levels of transcription of their target gene in all cell types. (See paragraph 0331). In view of the unpredictability of the transgenic art these embodiments are not deemed to be enabled.

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As a suggestion, amendment of the claim to recite "isolated eukaryotic or prokaryotic host cell" will be sufficient to overcome this rejection.

4. Claims 17, 19-21, and 28-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 17, 19-21 and 28-33 recite an isolated DNA encoding a megakaryocyte differentiation factor having an amino acid sequence the same as the native amino acid sequence of a megakaryocyte differentiation factor according to claim 6, an amino acid sequence wherein one or more than one amino acid residues is deleted, replaced, or added, or a combination of these modifications.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 34 alone is insufficient to describe the genus. One of skill in the art would reasonably

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conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants are respectfully directed to *In re Duel* 34 USPQ2d 1210 (CAFC 1995), which clearly shows that a protein can be anticipated by a reference which discloses that protein, but it does not anticipate or render obvious the DNA encoding the protein. Likewise, Applicants are attempting to claim a DNA of undisclosed structure. Without description of the DNA molecule, the written description requirement is not satisfied.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 17, 19, 21, 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Hermona et al.

The claims are directed to an isolated DNA encoding a megakaryocyte differentiation factor having an amino acid sequence the same as the native amino acid sequence of a megakaryocyte differentiation factor according to claim 1, an amino acid sequence wherein one or more than one amino acid residue is deleted, replaced, or added, or a combination of these modifications.

Hermona (EP 354989) disclose of isolated DNA encoding a megakaryocytopoietin, as well as vectors, host cells, and methods of expressing the protein recombinantly. (See abstract and claims).

In view that the DNA molecule disclosed by Hermona encodes a megakaryocyte differentiation protein with one or more “deletions, replacements, or insertions” compared to the factor recited in claim 1, the disclosure of Hermona is deemed to anticipate the claimed invention. Furthermore, in view that the hybridization conditions are not set forth in claims 30-31, the DNA of Hermona is deemed to be capable of hybridizing under certain low stringency conditions and therefore anticipatory of claims 30-31 as well.

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Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6. Claims 16 and 18 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1 and 3 of prior U.S. Patent No. 5,874,253. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 17, 19-21, and 28-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,874,253. Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims encompasses DNA molecules encoding a megakaryocyte differentiation factor.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached

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on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Primary Examiner

September 3, 2003